

From the INTERNATIONAL BUREAU

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PCTNOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

FENSTER, Paul
FENSTER & COMPANY, INTELLECTUAL PROPERTY
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ISRAËL**RECEIVED**

21 OCT 2007

FILE No. 34506

G.E. EHRLICH (1995) LTD.

Date of mailing (day/month/year) 27 September 2007 (27.09.2007)		
Applicant's or agent's file reference 470/05127		IMPORTANT NOTICE
International application No. PCT/IL2006/000345	International filing date (day/month/year) 16 March 2006 (16.03.2006)	
		Priority date (day/month/year) 18 March 2005 (18.03.2005)
Applicant METACURE (USA) INC. et al		

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Simin Baharlou
Facsimile No. +41 22 338 82 70	e-mail: pi09.pct@wipo.int

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 470/05127	FOR FURTHER ACTION	See item 4 below
International application No. PCT/IL2006/000345	International filing date (<i>day/month/year</i>) 16 March 2006 (16.03.2006)	Priority date (<i>day/month/year</i>) 18 March 2005 (18.03.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant METACURE (USA) INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Date of issuance of this report 18 September 2007 (18.09.2007)</p> <p>Authorized officer</p> <p style="text-align: center; font-size: 1.2em;">Simin Baharlou</p> <p>e-mail: pt09.pct@wipo.int</p>
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
PAUL FENSTER
FENSTER & COMPANY, INTELLECTUAL PROPERTY LTD.
P.O. BOX 10256
PETACH TIKVA, ISRAEL 49002

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 470/05127		Date of mailing (day/month/year) 20 APR 2007
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/IL06/00345	International filing date (day/month/year) 16 March 2006 (16.03.2006)	Priority date (day/month/year) 18 March 2005 (18.03.2005)
International Patent Classification (IPC) or both national classification and IPC IPC: A61N 1/05(2006.01) USPC: 607/40		
Applicant METACURE INC.		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 28 March 2007 (28.03.2007)	Authorized officer Carl Layno <i>Sharon W. Greenough</i> Telephone No. 571-272-2975
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL06/00345

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL06/00345

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

I. Statement

Novelty (N)	Claims <u>2-10, 13, 20, 22, 24 and 26-28</u>	YES
	Claims <u>1, 11, 12, 14-19, 21, 23 and 25</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-28</u>	NO
Industrial applicability (IA)	Claims <u>1-28</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL06/00345

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1, 11, 12, 14-19, 21, 23 and 25 lack novelty under PCT Article 33(2) as being anticipated by Cates et al. (US 2004/0230273, hereinafter Cates). Cates discloses an implant device 200 for electrical stimulation of the body that includes a coating 420 which changes properties after being inserted into the body, such that less irritation is felt by the body (par. 0047). The lead is also inherently capable of being inserted into the pancreas, which is viewed as functional language found in the claims.

Regarding claim 11, Cates discloses the coating (read as a sleeve) surrounds the electrode, while leaving it electrically active (par. 0008).

Regarding claims 12 and 14, once the lead is inserted in the pancreas, it will inherently have a better mechanical coupling since it is in contact with the pancreas. Furthermore, as more and more of the sleeve is inserted into the pancreas, the sleeve/coating is considered to "expand."

Regarding claims 15, 16 and 25, the ability of the sleeve/coating to be glued, become less coupled to the pancreas, and hold at least 100 microcoulombs of ions is considered functional language that the lead of Cates is inherently capable of performing.

Regarding claim 18, Cates discloses that the device may have mechanical memory such that it becomes flexible and takes a predetermined position once it has been inserted in the body (par. 0030).

Regarding claim 23, the lead of Cates is considered to be sufficiently long and flexible to exert a weak force on the body.

Claims 13, 22, 24, 26 and 27 lack an inventive step under PCT Article 33(3) as being obvious over Cates. Cates, as described above, discloses the applicant's basic invention with the exception of including tines and coupling to the body with a resistance of 20 Ohms. It is notoriously old and well known in the art to include tines on an implantation device in order to ensure adequate fixation at the implantation site. Furthermore, upon reviewing the specification of the current application, the examiner can find no disclosure that having the resistance of the coupling be less than 20 Ohms; it is merely given as an example. Since Cates will inherently couple to the body with a resistance, and would perform equally well as the implant device in the current application based on the fact that the applicant has not disclosed that the 20 Ohm threshold is for any particular purpose, the coupling resistance is considered an obvious design choice.

Claims 2-10 lack an inventive step under PCT Article 33(3) as being obvious over Cates in view of Osypka (US 2005/0033396). Cates

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL06/00345

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

as described above, discloses the applicant's basic invention with the exception of utilizing an inserting element with the implant device. Attention is directed to the secondary reference of Osypka, which discloses an electrode 2 with stiffening elements 7 and 9 that extend through the electrode. Furthermore, there is a knot that helps secure the thread 9 to the device (see figure 7 and claim 41) that once cut would free the electrode. Therefore, it would have been obvious to combine the implant device of Cates using the introduction structure and techniques of Osypka since this was a known structure and method for inserting electrodes into the body, and would allow for multiple electrodes to be inserted simultaneously.

Claim 20 lacks an inventive step under PCT Article 33(3) as being obvious over Cates in view of Machek et al. (US 5,954,761, hereinafter Machek). Cates, as described above, discloses the applicant's basic invention with the exception of using sugar as the coating. Attention is directed to the secondary reference of Machek, which discloses the use of sugar as a dissolvable coating on an implantable device (see col. 5, lines 38-57). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the lead of Cates to include the sugar coating of Machek since it is a biocompatible material that is an art-recognized equivalent for implantable coatings.

Claim 28 lacks an inventive step under PCT Article 33(3) as being obvious over Cates in view of Harel et al. (WO 2004/021858, hereinafter Harel). Cates, as described above, discloses the applicant's basic invention with the exception of explicitly teaching inserting the lead into the pancreas. Attention is directed to the secondary reference of Harel, which discloses inserting an electrode in the pancreas (page. 50, lines 25-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method of Cates by inserting the electrode into the pancreas as taught by Harel in order to blood glucose levels.

Claims 1-28 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.